K083464

510(k) SUMMARY – Premier CAMPY

JAN 30 2009

510(k) number:	
Submitter:	Meridian Bioscience: Inc.
Submitter's address:	3471 River Hills Drive Cincinnati, OH 45244
Contact:	Susan Rolih
Contact number:	(513) 271 3700
Date of preparation:	November 18, 2008
Device name:	Premier CAMPY
Common name:	EIA for Campylobacter
Classification name:	Campylobacter ssp. LQP, CFR section 866.3110
Predicate device:	K982315, ProSpecT Campylobacter EIA
Reference comparator	Bacterial culture

Description of the device:

Premier CAMPY is an in vitro diagnostic, microwell-based enzyme-linked immunoassay for the detection of common antigens found on *Campylobacter jejuni* and *C. coli* in stool samples from patients with signs and symptoms of Campylobacteriosis. The assay is intended to be used by hospital and reference laboratories to test for bacterial colonization. It is used in conjunction with information obtained from the patient's clinical symptoms and with other tests to diagnose Campylobacter infection. The assay consists of Premier CAMPY microwells coated with specific antibodies (capture antibodies), Premier CAMPY Enzyme Conjugate, Premier CAMPY Sample Diluent/Negative Control, Premier 20X Wash Buffer III, Premier Substrate Solution I, Premier Stop Solution I and Premier CAMPY Positive Control.

No calibrators are used with this device.

Intended use:

Premier CAMPY enzyme immunoassay (EIA) is an *in vitro* qualitative procedure for the detection of specific Campylobacter antigens in stool samples from patients with signs and symptoms of gastroenteritis. Premier CAMPY detects *C. jejuni* and *C. coli* in human stool that may be either unpreserved or preserved in Cary Blair-based transport media. Test results are to be used in conjunction with information obtained from the patient's clinical evaluation and other diagnostic procedures.

Premier CAMPY is intended for use in hospital, reference or state laboratory settings. The device is not intended for point-of-care use.

Comparison to predicate device:

Item	*Premier CAMPY*	*Predicate Device ProSpecT Campylbacter*
Assay type	EIA	EIA
Intended use		
Qualitative/Quantitative	Qualitative	Qualitative
Screening, diagnostic or identification test	Diagnostic	Diagnostic
Calibrator	No	No
Monitoring therapy	No	No
Reagents/components		
Microwells	Yes	Yes
Sample Diluent	Yes	Yes
Enzyme Conjugate	Yes	Yes
Wash Buffer	Yes	Yes
Substrate	Yes	Yes
Stop Solution	Yes	Yes
Positive Control	Yes	Yes
Negative Control	Yes	Yes
Species detected		
C. jejuni	Yes	Yes
C. coli	Yes	Unk
C. lari	No	No
C. fetus	No	No
Reading method		
Visual	Yes	Yes
Spectrophotometric	Yes	Yes
End point	Pos = definite yellow color Neg = Colorless to very faint yellow	Pos = yellow color Negative = Colorless
Calibrator	No	No
Equipment	General laboratory semiautomated washer (optional) General laboratory spectrophotometer (optional)	General laboratory semiautomated washer (optional) General laboratory spectrophotometer (optional) StatFax microplate incubator/shaker (optional)

Comparison to predicate cont'd

Item	*Premier CAMPY*	*Predicate Device ProSpecT Campylobacter*
Antibody sources		
Solid phase (microplate)	Mouse monoclonal	Rabbit polyclonal
Enzyme conjugate	Mouse monoclonal	Rabbit polyclonal
Sample Types		
Human stool (direct)	Yes	Yes
Broth culture	No	Yes
Endpoint determinations		
Positive (dual wavelength)	Yes ≥ 0.100	Yes ≥ 0.140
Negative (dual wavelength)	Yes < 0.100	Yes < 0.100
Indeterminant (dual wavelength)	None	Yes 0.100 to 0.139

Performance comparison – Nonclinical tests

Interference testing

Selected drugs and other nonmicrobial substances that might be present in stool samples from healthy persons or patients with signs and symptoms of gastroenteritis were added to three positive and three negative samples. The samples were inoculated with *C. jejuni* near the assay's limit of detection (LoD). The final concentrations of the substances in the samples were as follows: Barium sulfate (5 mg/mL); fecal fat (equivalent to 2.65 mg stearic plus 1.3 mg palmitic acids per mL), hemoglobin (as methhemoglobin) (3.2 mg/mL), Imodium AD® (0.00667 mg/mL), Kaopectate® (0.87 mg/mL), mucin (3.33 mg/mL), Mylanta® (4.2 mg/mL), Pepto-Bismol® (0.87 mg/mL), Prilosec® (0.5 mg/mL), Tagamet® (0.5 mg/mL), TUMS® (0.5 mg/mL), whole blood (5% v/v). The spiked samples were tested in parallel with an unspiked dilution control for reference. All samples were tested in triplicate. None of the potentially interfering substances met the criteria for an interferent.

Crossreactivity study

Microorganisms that were present as normal intestinal flora or associated with gastroenteritis were evaluated as to their effects on assay performance. Fungus and bacteria were tested at final concentrations in human stool of 1.1×10^9 CFU/mL. Viruses were tested at final concentrations of 1.3×10^4 to 3.1×10^6 $TCID_{50}$/mL. None of the following organisms in stool reacted with Premier CAMPY:

Aeromonas hydrophila, Bacteroides fragilis, Campylobacter fetus, C. lari, Candida albicans, Clostridium difficile, C. perfringens, Enterobacter cloacae, Enterococcus faecalis, Escherichia coli, E. coli O157:H7, *E. fergusonii, E. hermannii, Helicobacter pylori, Klebsiella pneumoniae, Lactococcus lactis, Listeria monocytogenes, Peptostreptococcus anaerobius, Plesiomonas shigelloides, Proteus vulgaris, Pseudomonas aeruginosa, P. fluorescens,* Salmonella Groups B-E, *Serratia liquefaciens, S. marcescens, Shigella boydii, S. dysenteriae, S. flexneri, S. sonnei, Staphylococcus aureus, S. epidermidis, Vibrio parahaemolyticus, Yersinia enterocolitica,* Adenovirus Types 40 and 41, Coxsackievirus, Echovirus, Rotavirus

Performance comparison – Clinical tests

The performance of Premier CAMPY was established in clinical trials using bacterial culture as the reference comparator method. Four independent test sites located in the Western, Midwestern and Southeastern regions of the United States tested a total of 2073 qualified patient samples. Of these, 166 were retrospective frozen samples. The majority (1862/2073) were collected in a Cary Blair-based transport and preservative medium. The remaining 211 samples were tested in the unpreserved state. Samples were collected from males (41%) and females (57%). In the case of 2% of the patients, the sex was not known. The age groups of the patients ranged from less than one month of age to 97 years. No differences in test performance were observed based on patient age or sex. The following tables show the assay performance by clinical site, patient age and sample type.

Table 1. Performance characteristics by clinical site

	Positive Samples			Negative Samples		
Site	**Premier/ Culture**	**Sensitivity %**	**95% CI**	**Premier/ Culture**	**Specificity %**	**95% CI**
Site 1	22/23	95.7%	79.0 – 99.2%	189/193	97.9%	94.8 – 99.2%
Site 2	0/0	N/A	N/A	51/51	100%	93.0 – 100%
Site 3	26/27	96.3%	81.7 – 99.3%	1429/1511	94.6%	93.3 – 95.6%
Site 4	11/11	100%	74.1 – 100%	255/257	99.2%	97.2 – 99.8%
Total Sites	59/61	96.7%	88.8 – 99.1%	1924/2012	95.6%	94.6 – 96.4%

Table 2. Performance characteristics by patient age

	Positive Samples			Negative Samples		
Patient Age	**Premier/ Culture**	**Sensitivity %**	**95% CI**	**Premier/ Culture**	**Specificity %**	**95% CI**
Birth to 1 month	0/0	N/A	N/A	12/13	92.3%	66.7 – 98.6%
>1 month to 2 years	3/3	100%	43.9 – 100%	338/348	97.1%	94.8 – 98.4%
>2 years to 12 years	5/5	100%	56.6 – 100%	374/388	96.4%	94.0 – 97.8%
>12 years to 21 years	2/2	100%	34.2 – 100%	139/145	95.9%	91.3 – 98.1%
>21 years	32/34	94.1%	80.9 – 98.4%	1052/1109	94.9%	93.4 – 96.5%
Not Defined	17/17	100%	81.6 – 100%	9/9	100%	70.1 – 100%

Table 3. Performance characteristics by sample type (preserved vs unpreserved)

	Positive Samples				Negative Samples		
Specimen Type	Premier/ Culture	Sensitivity %	95% CI		Premier/ Culture	Specificity %	95% CI
Preserved	42/43	97.7%	87.9 – 99.6%		1733/1819	95.3%	94.2 – 96.2%
Unpreserved	17/18	94.4%	74.2 – 99.0%		191/193	99.0%	96.3 – 99.7%

Table 4. Performance of fresh vs frozen samples

	Positive Samples				Negative Samples		
Fresh/Frozen	Premier/ Culture	Sensitivity %	95% CI		Premier/ Culture	Specificity %	95% CI
Fresh	17/18	94.4%	74.2 – 99.0%		1810/1889	95.8%	94.8 – 96.6%
Frozen	42/43	97.7%	87.9 – 99.6%		114/123	92.7%	86.7 – 96.1%

Analytical sensitivity

The analytical sensitivity of this assay for *C. jejuni* and *C. coli* was based on 45 tests for each measurand and with a stated probability (eg, 95%) of obtaining positive responses at the following levels of the measurands: *C. jejuni* 1.2×10^6 cells/mL; *C. coli* 8.0×10^6 cells/mL.

Reproducibility

Assay precision, intra-assay variability and inter-assay variability were assessed with a reference panel prepared from moderate positive (n = 2), negative (n = 2), high negative (n = 3) and low positive (n = 3) samples. High negative, low positive and moderate positive samples were prepared by inoculating negative stool matrix with known quantities of *C. jejuni*. In the case of low positive and high negative samples, the inoculum was added at concentrations that were at, or just below, the assay LoD. Aliquots of each panel were tested for five days, twice each day at three different test sites (Sites A, B and C). At least two technologists performed testing at each site.

As can be seen in Tables 5 – 9, the expected results were obtained 100% of the time.

Table 5. Site A data

Sample ID	Sample Qual. Result	Lot under test – 618096.003									
		Day 1 Run 1 TECH 1	Day 1 Run 2 TECH 2	Day 2 Run 1 TECH 1	Day 2 Run 2 TECH 2	Day 3 Run 1 TECH 1	Day 3 Run 2 TECH 2	Day 4 Run 1 TECH 1	Day 4 Run 2 TECH 2	Day 5 Run 1 TECH 1	Day 5 Run 2 TECH 2
PC	N/A	2.705	1.480	2.295	2.277	2.285	1.695	2.214	2.068	2.474	2.057
NC	N/A	0.020	0.017	0.025	0.019	0.020	0.019	0.023	0.025	0.021	0.021
MP 1	1.952	1.725	1.743	1.767	1.620	1.718	1.931	1.948	2.098	1.851	2.170
MP 2		1.753	1.698	1.656	1.518	1.755	1.895	1.938	1.986	1.931	2.191
LP 1	0.197	0.240	0.205	0.170	0.153	0.168	0.211	0.205	0.245	0.220	0.254
LP 2		0.186	0.196	0.153	0.164	0.146	0.191	0.225	0.225	0.172	0.234
LP 3		0.187	0.203	0.161	0.168	0.152	0.205	0.192	0.243	0.171	0.239
HN 1	0.054	0.026	0.040	0.026	0.032	0.035	0.039	0.032	0.045	0.041	0.059
HN 2		0.027	0.056	0.026	0.027	0.023	0.046	0.033	0.038	0.034	0.059
HN 3		0.026	0.038	0.026	0.029	0.019	0.047	0.026	0.040	0.039	0.062
WN 1	0.019	0.013	0.016	0.014	0.017	0.014	0.014	0.011	0.023	0.018	0.012
WN 2		0.015	0.018	0.013	0.013	0.011	0.011	0.015	0.017	0.016	0.015
Average high negative value		0.026	0.045	0.026	0.029	0.026	0.044	0.030	0.041	0.038	0.060
Average low positive value		0.204	0.201	0.161	0.162	0.155	0.202	0.207	0.238	0.188	0.242
Percent Correlation		100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Correlation of cut off Specimens		100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Legend: PC = positive control, NC = negative control; MP = moderate positive; LP = low positive; HN = high negative; WN = weak or low negative

Table 6. Site B data

Sample ID	Sample Qual. Result	Lot under test -- 618096.003									
		Day 1 Run 1 TECH 3	Day 1 Run 2 TECH 4	Day 2 Run 1 TECH 3	Day 2 Run 2 TECH 4	Day 3 Run 1 TECH 3	Day 3 Run 2 TECH 5	Day 4 Run 1 TECH 3	Day 4 Run 2 TECH 4	Day 5 Run 1 TECH 3	Day 5 Run 2 TECH 6
PC	N/A	1.577	1.686	2.117	1.974	1.278	1.802	1.747	1.548	0.922	2.051
NC	N/A	0.011	0.003	0.015	0.014	0.022	0.011	0.018	0.009	0.018	0.016
MP 1	1.952	1.635	1.769	2.542	1.977	2.017	1.853	0.820	1.661	1.515	1.542
MP 2		1.967	1.801	2.393	2.104	1.939	1.757	1.399	1.831	1.532	1.563
LP 1	0.197	0.214	0.195	0.269	0.239	0.283	0.229	0.218	0.219	0.216	0.200
LP 2		0.242	0.177	0.292	0.245	0.264	0.276	0.179	0.216	0.222	0.178
LP 3		0.199	0.205	0.286	0.266	0.260	0.266	0.177	0.223	0.196	0.194
HN 1	0.054	0.039	0.020	0.057	0.042	0.055	0.051	0.044	0.035	0.044	0.034
HN 2		0.096	0.031	0.040	0.061	0.052	0.060	0.040	0.043	0.047	0.035
HN 3		0.068	0.017	0.048	0.036	0.049	0.041	0.048	0.053	0.048	0.038
WN 1	0.019	0.034	-0.008	0.014	0.013	0.018	0.010	0.018	0.017	0.018	0.010
WN 2		0.015	0.008	0.015	0.018	0.020	-0.003	0.015	0.015	0.015	0.011
Average high negative value		0.068	0.023	0.048	0.046	0.052	0.051	0.044	0.044	0.046	0.036
Average low positive value		0.218	0.192	0.282	0.250	0.269	0.257	0.191	0.219	0.211	0.191
Percent Correlation		100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Correlation of cut off Specimens		100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Legend: PC = positive control, NC = negative control; MP = moderate positive; LP = low positive; HN = high negative; WN = weak or low negative

Table 7. Site C data

Sample ID	Sample Qual. Result	Lot under test -- 618096.003									
		Day 1 Run 1 TECH 7	Day 1 Run 2 TECH 8	Day 2 Run 1 TECH 7	Day 2 Run 2 TECH 8	Day 3 Run 1 TECH 7	Day 3 Run 2 TECH 8	Day 4 Run 1 TECH 7	Day 4 Run 2 TECH 8	Day 5 Run 1 TECH 7	Day 5 Run 2 TECH 8
PC	N/A	2.165	2.003	2.145	2.144	1.993	2.068	2.109	1.916	2.210	1.854
NC	N/A	0.034	0.039	0.032	0.034	0.027	0.034	0.026	0.032	0.031	0.030
MP 1	1.952	1.035	1.179	2.293	2.144	1.584	1.610	1.957	1.442	1.836	1.614
MP 2		1.006	1.158	2.188	2.467	1.615	1.691	2.062	1.515	1.656	1.811
LP 1	0.197	0.116	0.185	0.290	0.308	0.213	0.209	0.222	0.181	0.206	0.252
LP 2		0.128	0.159	0.310	0.327	0.232	0.212	0.239	0.195	0.213	0.223
LP 3		0.116	0.153	0.269	0.303	0.208	0.221	0.206	0.180	0.207	0.201
HN 1	0.054	0.036	0.058	0.072	0.085	0.055	0.068	0.052	0.059	0.058	0.053
HN 2		0.050	0.060	0.070	0.080	0.061	0.052	0.051	0.050	0.061	0.058
HN 3		0.045	0.064	0.070	0.066	0.055	0.055	0.053	0.047	0.059	0.048
WN 1	0.019	0.028	0.034	0.027	0.031	0.025	0.027	0.032	0.026	0.029	0.028
WN 2		0.033	0.034	0.028	0.030	0.025	0.031	0.030	0.026	0.031	0.026
Average high negative value		0.044	0.061	0.071	0.077	0.057	0.058	0.052	0.052	0.059	0.053
Average low positive value		0.120	0.166	0.290	0.313	0.218	0.214	0.222	0.185	0.209	0.225
Percent Correlation		**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**
Correlation of cut off Specimens		**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**

Legend: PC = positive control, NC = negative control; MP = moderate positive; LP = low positive; HN = high negative; WN = weak or low negative

Table 8. Intra- and Inter-assay variability data for all sites

Panel Members	Sample N	Grand Mean AL	Between-Day		Between-Run		Between-Site		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
PC	30	1.962	0.115	5.9%	0.157	8.0%	0.257	13.1%	0.361	18.4%
MP 1	30	1.753	0.200	11.4%	0.206	11.7%	0.095	5.4%	0.354	20.2%
MP 2	30	1.793	0.174	9.7%	0.168	9.4%	0.066	3.7%	0.321	17.9%
LP 1	30	0.218	0.017	7.7%	0.017	7.7%	0.011	4.8%	0.041	18.6%
LP 2	30	0.214	0.024	11.3%	0.023	10.9%	0.022	10.1%	0.048	22.4%
LP 3	30	0.209	0.024	11.5%	0.025	11.9%	0.018	8.5%	0.043	20.6%

Legend: N = number, AL = all, SD = standard deviation, CV = coefficient of variation, PC = positive control, MP = moderate positive, LP = low positive

Tables 9A-C. Intra- and Inter-assay variability data by site

A. Site A

Panel Members	Sample N	Grand Mean AL	Between-Day		Between-Tech		Total	
			SD	%CV	SD	%CV	SD	%CV
PC	10	2.155	0.123	5.7%	0.339	15.7%	0.356	16.5%
MP 1	10	1.857	0.153	8.3%	0.078	4.2%	0.178	9.6%
MP 2	10	1.832	0.188	10.2%	0.036	2.0%	0.194	10.6%
LP 1	10	0.207	0.031	15.0%	0.009	4.4%	0.035	16.7%
LP 2	10	0.189	0.027	14.1%	0.018	9.6%	0.031	16.5%
LP 3	10	0.192	0.021	10.9%	0.028	14.4%	0.031	16.2%

B. Site B

Panel Members	Sample N	Grand Mean AL	Between-Day		Between-Tech		Total	
			SD	%CV	SD	%CV	SD	%CV
PC	10	1.670	0.220	13.2%	0.201	12.0%	0.365	21.8%
MP 1	10	1.733	0.388	22.4%	0.039	2.2%	0.440	25.4%
MP 2	10	1.829	0.276	15.1%	0.025	1.3%	0.293	16.0%
LP 1	10	0.228	0.025	11.0%	0.017	7.3%	0.028	12.4%
LP 2	10	0.229	0.037	16.1%	0.015	6.6%	0.042	18.3%
LP 3	10	0.227	0.039	17.2%	0.005	2.2%	0.039	17.0%

C. Site C

Panel Members	Sample N	Grand Mean AL	Between-Day		Between-Tech		Total	
			SD	%CV	SD	%CV	SD	%CV
PC	10	2.061	0.054	2.6%	0.090	4.4%	0.116	5.6%
MP 1	10	1.669	0.396	23.7%	0.101	6.1%	0.399	23.9%
MP 2	10	1.717	0.443	25.8%	0.016	0.9%	0.445	25.9%
LP 1	10	0.218	0.054	24.6%	0.012	5.7%	0.055	25.4%
LP 2	10	0.224	0.062	27.8%	0.001	0.4%	0.060	27.0%
LP 3	10	0.206	0.054	26.3%	0.007	3.6%	0.053	25.6%

Legend: N = number, AL = all, SD = standard deviation, CV = coefficient of variation, PC = positive control, MP = moderate positive, LP = low positive

Conclusions

Premier CAMPY:

1. Can be used to detect *C. jejuni and C. coli.* in human stool.
2. The test is diagnostic for the presence of *C. jejuni* and *C. coli.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 30 2009

Ms. Susan Rolih
Senior Vice President, RA/QA
Meridian Bioscience, Inc
3471 River Hills Drive
Cincinnati, OH 45244

Re: k083464
Trade/Device Name: Premier CAMPY
Regulation Number: 21 CFR § 866.3110
Regulation Name: Campylobacter fetus serological reagents
Regulatory Class: Class I
Product Code: LQP
Dated: December 15th, 2008
Received: December 19th, 2008

Dear Ms. Rolih:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication(s) for Use

510(k) Number (if known):

Device Name: Premier CAMPY

Indication For Use:

Premier™ CAMPY enzyme immunoassay (EIA) is an in vitro qualitative procedure for the detection of specific *Campylobacter* antigens in stool samples from patients with signs and symptoms of gastroenteritis. Premier CAMPY detects *C. jejuni* and *C. coli* in human stool that may be either unpreserved or preserved in Cary Blair-based transport media. Test results are to be used in conjunction with information obtained from the patient's clinical evaluation and other diagnostic procedures.

Premier CAMPY is intended for use in hospital, reference or state laboratory settings. The device is not intended for point-of-care use.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K083464